DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Mr. David Westlin
Chief Compliance Officer
Senior Director of Regulatory Affairs
Arizant Healthcare Incorporated
10393 West 70th Street
Eden Prairie, Minnesota 55344

JAN 1 0 2017

Re: K082217
Trade/Device Name: Ranger Rapid Flow Blood/Fluid Warming System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: October 1, 2008
Received: October 2, 2008

Dear Mr. Westlin:

This letter corrects our substantially equivalent letter of October 6, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name:

Ranger Rapid Flow Blood/Fluid Warming System

Indications For Use:

The Ranger Rapid Flow blood/fluid warming system is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Pi-chun Lin

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082217

K082217

OCT 0 6 2008

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. The device is a Class II device called the Ranger® Rapid Flow™ blood/fluid warming system.

Submitter
Arizant Healthcare Inc.
10393 West 70th Street, Eden Prairie, MN 55344

Date Prepared
July 31, 2008

Trade/Proprietary Name
Ranger® Rapid Flow™ blood/fluid warming system

Common/Usual Name
Blood/Fluid Warmer with Pressure Infusor

Classification Name
Warmer, Thermal, Infusion Fluid

Predicate Devices
Arizant Healthcare Inc. Bair Hugger blood/fluid warmer (K973741)
Level 1® H-1028 Fluid Warming System (BK020043)

Intended Use
The Ranger Rapid Flow blood/fluid warming system is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients.

Description of Device

The Ranger Rapid Flow blood/fluid warming system is a stand-alone system that warms fluid, detects fluid level within the bubble trap, controls a patient valve, and delivers high volumes of fluid under pressure. The warming system consists of warming plates, fluid detection, valve control, pressure infusors and a fluid warming disposable set.

Ranger Rapid Flow blood/fluid warming unit

The warming unit consists of the electronic control circuitry and aluminum plates contacted by heating elements, also known as dry-heat. With a setpoint of 42°C that is PID controlled, the displayed temperature is an average of the fluid and plate temperature.

The air detection has two sensors that detect the fluid level (absence of air) and controls a patient valve. If the fluid level is not adequate, the patient valve closes and stops flow to the patient. When the fluid level is adequate the patient valve opens, allowing the flow of fluid to the patient. This functionality is also tied to the operation of the pressure infusors. If the patient valve closes, the pressure is exhausted from the pressure infusors. Only if the fluid level is adequate and the valve is open can the pressure infusors be pressurized. The pressure infusor interface provides feedback to the user.

The pressure infusors accept solution bags ranging from 250cc to 1000cc. Each side of the pressure infusor is controlled independently. The pressure infusors are set to 300 mmHg and provide fluid under pressure to achieve a higher flow.

The system continuously monitors temperature and detects air in the fluid path to ensure safe operation and alarms at all unsafe conditions. The main panel on the front of the unit displays the temperature and status of the warming unit.

Ranger Rapid Flow disposable set

The disposable set is an integral component to the Ranger Rapid Flow blood/fluid warming system. The set has spike/filter drip chambers, heat exchanger, bubble trap, patient line with injection ports, tubing, luer locks, and other standard administration set components. The spike/drip chambers can be easily replaced during a procedure. There is an option for dual or triple spike disposable sets. The heat exchanger makes contact with the heating plates to warm the fluid. The bubble trap captures and vents air from the system. Sensors monitor the fluid level within the bubble trap and control a valve on the disposable to stop or allow flow to the patient.

Comparison of the Technological Characteristics of the New Device and Predicate Devices

The Ranger® Rapid Flow blood/fluid warming system is substantially equivalent to the Bair Hugger blood/fluid warmer (K973741) and Level 1® H-1028 Fluid Warming System (BK020043).

Comparison of Technological Features

Features	Ranger Rapid Flow Blood/Fluid Warming System	Bair Hugger Blood/Fluid Warmer	Level 1 H-1028 Fluid Warming System
Flow rates	KVO-1200 mL/min	KVO-500 mL/min	KVO-1400 mL/min
Method of operation	Aluminum plate heated by electrical resistance; disposable cassette contacts plates	Aluminum plate heated by electrical resistance; disposable cassette contacts plates	Fluids are warmed through the use of a sealed heat exchanger through which a recirculating solution flows.
Electronics	PID-controlled	PID-controlled	Uses water bath technology controlled electronics
Temperature Control	Electronically Controlled	Electronically Controlled	Electronically Controlled
Alarms	Audible and visual under and over temperature; alarms activate when temperature is at 25°C, at 45.5°C, and at 46°C.	Audible and visual under and over temperature; alarms activate when temperature is at 33°C, at 43°C, and at 46°C.	Audible and visual over temperature alarms activate when temperature is at 43.9°C.
Tubing	• 144" long, 0.185" min ID, 0.273 max OD. • Patient Line: 84" long, 0.185" min ID, 0.273 max OD.	• 144" long, 0.185" min ID, 0.273 max OD. • Patient Line: 84" long, 0.185" min ID, 0.273 max OD.	• 68" long, 0.185" max ID, 0.273" min ID. • Patient Line: 87" long, 0.185" min ID, 0.273 max OD.
Sterilization method	100% Ethylene Oxide, reference Isomedix Soft Cycle.	100% Ethylene Oxide, reference Isomedix Soft Cycle.	100% Ethylene Oxide, reference Isomedix Soft Cycle.
Disposable packaging	The disposable set will be manufactured and assemble in a filtered air environment. Prior to exiting the filtered air environment, each disposable set will be placed in a box and then sealed within a pouch. The pouch is made of polyethylene and tyvek header which have been proven to resist tearing or puncturing.	The disposable set is manufactured and assemble in a filtered air environment. Prior to exiting the filtered air environment, each disposable set will be placed in a box or sealed within a pouch. The pouch is made of polyethylene and tyvek header which have been proven to resist tearing or puncturing.	The disposable set is placed within a box.

Discussion of Nonclinical Studies and Clinical Tests

Clinical tests were not necessary regarding the use of the Ranger Rapid Flow blood/fluid warming system.

Conclusion

The Ranger Rapid Flow blood/fluid warming system has similar technological characteristics, components, and materials, and the same intended use as devices currently on the market. Therefore, because of the similarities to the predicate devices, Arizant Healthcare believes this new device does not raise any new safety or effectiveness issues.

Contact

David Westlin
Chief Compliance Officer and Senior Director of Regulatory Affairs, Arizant Healthcare Inc.